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May 14, 2004

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION (REVISED)

The undersigned journalist who reports FDA news to thousands of U.S. and foreign readers hereby submits this Citizen Petition pursuant to Sec. 701 of the Federal Food, Drug and Cosmetic Act, 21 USC § 371, the Freedom of Information Act, 5 USC § 552 and their implementing regulations.

The petitioner hereby requests the Commissioner of Food and Drugs to draft regulatory procedures and promulgate FDA policy for the fair, nondiscriminatory and objective treatment of all news media, whether print, broadcast or electronic (Internet) by the FDA Press Office and all other FDA offices having any contact whatever with the news media. Specifically, the petitioner requests the Commissioner to prohibit the practice of selectively inviting some, but not other, media organizations and individual journalists to participate in FDA-sponsored news conferences; to prohibit discrimination between print and broadcast media having access to FDA spokespersons (i.e., if FDA permits an employee to be interviewed by print media the agency may not discriminatorily prohibit that employee being interviewed by broadcast media, or *vice versa*, but the employee must be allowed to freely elect to exercise his or her own choice in the matter without management duress or reprisal); and to promulgate a policy of agency-wide openness to the news media to the fullest extent allowed by good management and the observance of law.

ACTIONS REQUESTED

Petitioner asserts that fundamental fairness requires FDA to treat all news media, including the trade press, fairly and equitably. To this end, petitioner requests the Commissioner to take the following actions:

(1) Publish draft regulatory procedures requiring the FDA Press Office and all other offices through the agency that have frequent contact with representatives of the news media, including the trade press and broadcast news media, to treat all such persons and their organizations with fairness, candor and truthfulness;

(2) Publish and disseminate throughout the agency a Policy Statement stating that it is the policy of Food and Drug Administration to be open and candid with all news media to the fullest extent permitted by law, that FDA employees are not permitted to discriminate between kinds of news media or news media organizations, that while no FDA employee can be compelled by management to communicate with the news media neither may any FDA employee be penalized by management for legally communicating with the news media.

STATEMENT OF GROUNDS

Petitioner has noticed increasing lapses of fairness, candor and openness in the agency's communications and relationships with the news media. For example, on Thursday, May 6, 2004, Associate Commissioner for Public Affairs Lawrence Bachorik prohibited the CDER Trade Media Liaison staff from issuing invitations to all of its

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constituents to participate in a telephone news conference hosted by Mr. Bachorik on the subject of the non-approval of the Plan B over-the-counter emergency contraceptive, with CDER acting director Steven Galson. Mr. Bachorik authorized the participation of only the *Pink Sheet*, the *Tan Sheet*, *FDA Week*, *JAMA* and Web MD as "trade press" plus the general mass media. On information and belief, Mr. Bachorik's exclusion of others was concurred in by Associate Commissioner for External Relations Peter Pitts. Excluding some media representatives amounts to favoritism toward those admitted, as well as an illegal act of discrimination and violence to the First Amendment of the U.S. Constitution because it "abridges" the freedom of those excluded.

Mr. Bachorik conducted an extremely abbreviated conference and left many participants cut off and unable to ask their questions. Because of the conference's arbitrary brevity, had the full cadre of all bona fide reporters covering FDA been permitted access, most would have been unable to ask as many questions as the subject matter (non-approval of Plan B) had aroused. Thus, this news conference was an exercise more of attempted "damage control" than of a free and full exploration of all the public issues presented by the non-approval.

As an example of the autocratic, discriminatory and ridiculous nature of Mr. Bachorik's management of the conference, the following exchange took place:

Monika Konrad, ABC News: *You guys have said you're not going to do an interview with ABC News, and I would assume that would be with all broadcasters. Can I ask you why the FDA has decided not to go on-camera with broadcast today?*

Larry Bachorik: *Ah, um, Monica .. uh, um ... we're not — this is Larry again — we're um, declining broadcast interviews for security reasons, and that's all we can say about that.*

Monika: *For security reasons? Can you elaborate on that?*

Larry: *That's all I can say about that.*

Monika: *For security reasons. I guess we would need a further explanation of that.*

Larry: *I, I think, um, I think we're ready for the next question.*

To most journalists listening, Mr. Bachorik's invocation of "security" as the only reason not to admit a cameraman in to Dr. Galson's office or conference room for an interview must have sounded absurd. Did he think the cameraman might inflict violence upon Dr. Galson? Mr. Bachorik's refusal to explain what he meant by "security" served as a tacit acknowledgment that his position was indefensible.

In the absence of any evidence to the contrary, FDA needs to publicly acknowledge that the news media with whom it deals are conscientious about informing the public. Impeding public full, open dissemination of information about FDA activities as the above press conference did is a disservice to the media and its readers and viewers. The FDA Press Office has become an instrument of manipulation, unfairness, "spin" and attempted management of the news media. Incidents like the one cited above — which is merely the worst and most recent, not the only, example — form a pattern of abuse by FDA of the First Amendment freedom of the press. It is the media, not FDA, that determines what news about FDA the American public receives. In order to do its job as the Framers intended, agencies like FDA have a duty to be honest, open, fair, candid and non-manipulative.

FDA needs to be reminded of Thomas Jefferson's words: "... were it left to me to decide whether we should have government without newspapers, or newspapers without government, I should not hesitate a moment to prefer the latter." Current administrative trends and practices in the FDA Press Office do not show adequate respect for Jefferson's perspective. In short, the news media are not a public utility to be used however FDA chooses. This principle is established in the First Amendment to the U.S. Constitution.

CONCLUSION

The requested actions outlined in this Citizen Petition would accomplish a minimum standard of fair and adequate performance by the FDA Press Office and all other FDA employees who deal with the news media and would help the agency avoid present abuses of the First Amendment in this regard.

ENVIRONMENTAL IMPACT STATEMENT

The requested actions herein will not result in the production or distribution of any substance and, therefore, will not result in the introduction of any substance into the environment. The requested actions are therefore subject to the categorical exclusion of 21CFR § 25.24, and do not require the preparation of an environmental assessment.

ECONOMIC IMPACT

Petitioner will submit information on the economic impact of the requested actions if requested by the Commissioner.

CERTIFICATION

The undersigned certifies that, to the best of his knowledge and belief, this petition contains all information and views upon which it relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

James G Dickinson

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